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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,320	06/21/1999	SEISHI KATO	01997.004700	2154

7590 05/06/2003  
FITZPATRICK CELLA HARPER & SCINTO  
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NEW YORK, NY 10112-3801

EXAMINER  
SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/06/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/284,320

Applicant(s)

KATO ET AL.

Examiner

Jegatheesan Seharaseyon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002 and 17 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6,8 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6,8 and 12-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This Office action is in response to your request for withdrawal of the previous action filed on 12<sup>th</sup> of December (Paper No: 35). The Office acknowledges the Applicant's request for suspension of action for a period of three months filed on the 29<sup>th</sup> of October (Paper No: 32) with the request for continued examination (RCE). Therefore, the previous Office action dated 29<sup>th</sup> of November (Paper No: 34) is vacated.

Furthermore, a letter suspending prosecution for a period of 3 months was mailed to the Applicant on 2/5/03. This suspension ended on 5/5/03. Therefore, prosecution on the merits continues.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/02 has been entered. An action on the RCE follows.

3. Applicant's amendment filed under 37 CFR 1.116 on 9/3/02 has been entered. Claims 6, 8 and 12-18 are pending.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

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***Claim Rejections - 35 USC § 101, lack of utility rejection is maintained***

5. Applicant's arguments filed on 9/3/02 in Paper No: 29 in reference to claims 6, 8 and 12-18 have been fully considered but they are not persuasive. Thus, claims 6,8 and 12-18 are rejected under 35 USC 101 for lack of utility, for the reasons set forth in Paper Nos: 19, 22 and 28.

Applicant requests clarification for the position taken by the Office with respect to identifying genetic disorders. The Office stated in Paper No: 28, that, although using DNA markers to identify genetic disorders is credible, because specification did not disclose any disease associated with the instant invention it was found not to be specific or substantial. Neither the specification nor the prior art demonstrates a causal correlation or nexus of the claimed polypeptide or the nucleotide encoding it with any of the genetic conditions or disorders contemplated by the instant specification. Thus, there is no evidence of record that would provide for a method for diagnosing/identifying any of the genetic conditions or disorders. In addition, there is absolutely no evidence of record or any line of reasoning that would support a conclusion that the protein of the instant application is involved in any genetic disorder. Furthermore, the record fails to indicate any evidence of any biological activity for the instant invention.

Applicant further asserts that the human sequence of the instant invention is not found in normal cells and thus can identify both the existence of a disease state and the expectation of such disease state. However, there is no evidence in the specification to substantiate the expression pattern. Thus, in the absence of a nexus or

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correlation of the expression profile with a particular disease or cancer, the invention is incomplete. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 112, lack of enablement, rejection is maintained***

6. Applicant's last arguments of record were filed on 9/3/02 in Paper No: 29 in reference to rejection of claims 6, 8 and 12-18 under 35 USC 112, first paragraph. These arguments have been fully considered but they are not persuasive for reasons already of record in Paper Nos: 19, 22, 28 and paragraph 4 above.

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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### Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS  
May 2, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600